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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,487	08/23/2001	Robert F. Rioux	BSC-187 (1002/257)	1401

21323 7590 08/04/2003

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,487

Applicant(s)

RIOUX ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 9-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Evard et al. (WO 97/27898). Fig. 2' illustrates a coil segment with a middle portion **14** spaced from the proximal and distal windings and has a diameter less than the proximal and distal ends. Evard et al. disclose a covering or what can be interpreted as "webbing" such that a portion or the entire device is encapsulated or covered by the covering, page 33, lines 5-8. It can be interpreted from the disclosure of Evard on page 14, lines 22-25 that these coverings inhibit ingrowth of body tissue. Evard also discloses the coil

can be a biocompatible wire made from steel or nickel titanium, page 34, lines 1-3.

Evard additionally discloses that the different features of various embodiments are capable of being combined to form embodiments not shown, page 45, lines 31-36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Yachia et al. (5246445). Evard et al. is explained supra. However, Evard does not disclose a cross-sectional area of the wire within the range of 0.0079mm^2 to 7.1mm^2 or separation of the windings within the range of 0.5mm to 10mm or the use of hooks at each of the proximal and distal ends of the prosthetic device. Yachia et al. teach a cross-sectional area of 0.0079mm^2 to 0.785mm^2 and a separation of the windings with a range 0.5-2mm, col. 4, lines 44,45,49-52. Yachia et al. also teach (Fig. 1a) a stent with hooks 3 at both the proximal and distal ends of the coil body for connection to a delivery system, col. 6, lines 13-16. It would have been obvious to one of ordinary skill in the art to use a wire with the cross-sectional area and spacing distance of 0.5-2mm between windings as taught by Yachia et al. with the device of Evard et al. in order to provide some flexibility by having some distance between windings, but also some greater structural support with the larger cross-

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sectional area wire. It would also have been obvious to one of ordinary skill in the art to incorporate hooks at both proximal and distal ends of a stent as taught Yachia et al. in the device of Evard et al. such that the vessel apparatus does not dislodge from the instrument used to implant it. The addition of the hooks enables the surgeon to precisely place the vessel-opening device in its location without the apparatus being displaced during insertion.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Hachtman et al. (5645559). Evard et al. is explained supra. Evard does disclose that silicone can be used in sleeves placed on stent devices, page 17, lines 21-24. However, Evard does not disclose a low durometer silicone within the range of 0-60D. Hachtman et al. also teach that a silicone layer is placed on the stent to provide a barrier that prevents the growth of tissue through the stent and to support the flow of fluid through the lumen, col. 2, lines 14-18. Hachtman et al. also teach that low durometer silicone, such as 30D is placed on a stent, col. 4, lines 49-52. It would have been obvious to one of ordinary skill in the art to use a low durometer silicone as taught by Hachtman et al. for the silicone on Evard's vessel apparatus such that fluid flow is maintained through the lumen of the device while preventing tissue ingrowth.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-

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5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian Pellegrino

July 27, 2003

TC 3700, AU 3738

A handwritten signature in black ink that reads "Brian Pellegrino". The signature is written in a cursive style with a large, stylized 'P'.